



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2022-P-0069]

Determination That MICRONOR (Norethindrone Tablets, 0.35 Milligram) Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) has determined that MICRONOR (norethindrone tablets, 0.35 milligram (mg)) was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for norethindrone tablets, 0.35 mg, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Nikki Mueller, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6280, Silver Spring, MD 20993-0002, 301-796-3601, Nicole.Mueller@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(j)) allows the submission of an ANDA to market a generic version of a previously approved drug product. To obtain approval, the ANDA applicant must show, among other things, that the generic drug product: (1) has the same active ingredient(s), dosage form, route of administration, strength, conditions of use, and (with certain exceptions) labeling as the listed drug, which is a version of the drug that was previously approved, and (2) is bioequivalent to the listed drug. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

Section 505(j)(7) of the FD&C Act requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the “Approved Drug Products With Therapeutic Equivalence

Evaluations,” which is known generally as the “Orange Book.” Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug’s NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to FDA’s approval of an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

MICRONOR (norethindrone tablets, 0.35 mg) is the subject of NDA 016954, held by Janssen Pharmaceuticals Inc. (Janssen), and initially approved on January 2, 1973. MICRONOR is indicated for the prevention of pregnancy.

In a document dated June 6, 2018, Janssen notified FDA that the decision to withdraw MICRONOR (norethindrone tablets, 0.35 mg) from sale was based on business reasons and not for reasons of safety or efficacy. FDA moved the drug product to the “Discontinued Drug Product List” section of the Orange Book.

Aurobindo Pharma USA, Inc., submitted a citizen petition dated January 11, 2022 (Docket No. FDA-2022-P-0069), under 21 CFR 10.30, requesting that the Agency determine whether MICRONOR (norethindrone tablets, 0.35 mg) was withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that MICRONOR (norethindrone tablets, 0.35 mg) was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that MICRONOR (norethindrone tablets, 0.35 mg) was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of MICRONOR

(norethindrone tablets, 0.35 mg) from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have reviewed the available evidence and determined that this drug product was not withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list MICRONOR (norethindrone tablets, 0.35 mg) in the “Discontinued Drug Product List” section of the Orange Book. The “Discontinued Drug Product List” delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to MICRONOR (norethindrone tablets, 0.35 mg) may be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: June 24, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

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